

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of synbiotic capsule on the status of hematologic indices of anemia in women with iron deficiency anemia referring to in City Level Labs Mahallat

#### Protocol summary

##### Study aim

The effect of synbiotic capsule on hematologic status of anemia in with iron deficiency anemia referring to Imam Khomeini Hospital in Mahalat

##### Design

Trial without control group, simple randomization, without blinding

##### Settings and conduct

Workplace Design: Hospital Methods: 10% of the sample size was calculated and referrals from cases with iron deficiency anemia with a hemoglobin concentration of 10 to 12 mg / dl were recorded from the total list with a number ranging from 1 to 9. The baseline and the multiples of the sample will continue. The general information questionnaire, oral frequency questionnaire and ethical consent will be completed and a training session on dietary intake and supplement intake will be held for all women. All people are asked to notify the practitioner of the plan in the event of illness, medication, or any form of supplementation by the physician, or any changes that may affect the plan. Anthropometric measurements (including weight and height), biochemical variables (RBC, HB, HCT, MCV, MCH, MCHC, RDW, Ferritin, IRON, TIBC) and end of study will be reviewed. All women receive 2 capsules of synbiotic daily for 12 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 20-35 years old, with hemoglobin concentration greater than 12-12 mg / dl  
Exclusion criteria: no supplementation, blood loss within 3 months, disease

##### Intervention groups

Synbiotics Supplement

##### Main outcome variables

RBC , HB , HCT , MCV , MCH , MCHC , RDW index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190807044465N1**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

##### Registration date

2019-10-26, 1398/08/04

##### Registrant information

##### Name

sodabeh amiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 4322 3026

##### Email address

sodabehamiry@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of synbiotic capsule on the status of hematologic indices of anemia in women with iron deficiency anemia referring to in City Level Labs Mahallat

## Public title

The effect of synbiotic on the status of indices of anemia in women

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women with iron deficiency anemia referred to in City Level Labs Mahallat

### Exclusion criteria:

Women under 20 and over 35 years

## Age

From **20 years** old to **35 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

Biochemical variables including (RBC, HB, HCT, MCV, MCH, MCHC, RDW, Ferritin, IRON, TIBC

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics of Arak University of Medical Sciences

##### Street address

jomhhori Avenue - Jihad Construction Str

##### City

Mahallat

##### Province

Markazi

##### Postal code

37816-66369

## Approval date

2019-01-23, 1397/11/03

## Ethics committee reference number

IR.ARAKMU.REC.1398.088

## Health conditions studied

### 1

#### Description of health condition studied

Iron deficiency anemia

#### ICD-10 code

D50

#### ICD-10 code description

Iron deficiency anemia

## Primary outcomes

### 1

#### Description

RBC index

#### Timepoint

Baseline - 12 weeks after intervention

#### Method of measurement

Biochemical test

### 2

#### Description

HB index

#### Timepoint

Baseline - 12 weeks after intervention

#### Method of measurement

Biochemical test

### 3

#### Description

HCT index

#### Timepoint

Baseline - 12 weeks after intervention

#### Method of measurement

Biochemical test

### 4

#### Description

MCV index

#### Timepoint

Baseline - 12 weeks after intervention

#### Method of measurement

Biochemical test

### 5

#### Description

MCH index

#### Timepoint

Baseline - 12 weeks after intervention

#### Method of measurement

Biochemical test

## 6

### **Description**

MCHC index

### **Timepoint**

Baseline - 12 weeks after intervention

### **Method of measurement**

Biochemical test

## 7

### **Description**

RDW index

### **Timepoint**

Baseline - 12 weeks after intervention

### **Method of measurement**

Biochemical test

## 8

### **Description**

Ferritin index

### **Timepoint**

Baseline - 12 weeks after intervention

### **Method of measurement**

Biochemical test

## 9

### **Description**

IRON index

### **Timepoint**

Baseline - 12 weeks after intervention

### **Method of measurement**

Biochemical test

## 10

### **Description**

TIBC index

### **Timepoint**

Baseline - 12 weeks after intervention

### **Method of measurement**

Biochemical test

## 11

### **Description**

BMI index

### **Timepoint**

Baseline - 12 weeks after intervention

### **Method of measurement**

Balance and meter

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Women 20-35 years old with iron

deficiency anemia/ Synbiotic supplement as Familact capsule contains high levels (109 CFU) of different probiotics prescribed in doses of 500 mg / 2 daily / Bio Fermentation Company - Iran

### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital in Mahallat

##### **Full name of responsible person**

Sodabeh Amiri

##### **Street address**

Jomhori Street

##### **City**

Mahallat

##### **Province**

Markazi

##### **Postal code**

3781666369

##### **Phone**

+98 86 4322 2081

##### **Fax**

+98 86 4322 4288

##### **Email**

Sodabehamiry@yahoo.com

##### **Web page address**

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Fatemeh Azizi Soleiman

##### **Street address**

Jomhori Street

##### **City**

Mahallat

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Fax**

+98 86 4322 6979

##### **Email**

Sodabehamiry@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

640

##### **Is the source of funding the same sponsor organization/entity?**

No

##### **Title of funding source**

Arak Medical University  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Soudabeh Amiri  
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Expert  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
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Mahbobeh Rahmani  
**Position**  
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Master  
**Other areas of specialty/work**  
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Rahmani.mahbobeh@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

BMI, Biochemical index

### When the data will become available and for how long

3 Month

### To whom data/document is available

Researchers plan

### Under which criteria data/document could be used

prevention

### From where data/document is obtainable

laboratory  
**What processes are involved for a request to access data/document**

Visiting and doing tests  
**Comments**